

PATENT
ATTORNEY DOCKET NO. 07588/026002

Certificate of Mailing: Date of Deposit: March 11, 2004

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Tracy Simmons
Printed name of person faxing correspondence

Tracy Simmons
Signature of person faxing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Peter Wernet	Art Unit:	1636
Serial No.:	09/985,335	Examiner:	Quang Nguyen
Filed:	November 2, 2001	Customer No.:	21559
Title:	HUMAN CORD DERIVED UNRESTRICTED SOMATIC STEM CELLS (USSC)		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PETER WERNET UNDER 37 C.F.R. § 1.131
TO OVERCOME ERICES ET AL.

Under 37 C.F.R. § 1.131 and regarding the rejection of 1-10 and 13 for anticipation by *Erices et al.* (*Br. J. Haematol.* 109:235-242, April 2000; "Erices"), I declare:

1. I am the inventor of the subject matter described and claimed in the above-captioned patent application.

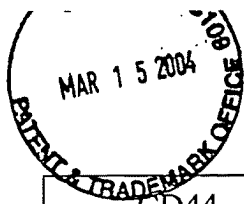
2. I have read and understood the Office action mailed September 11, 2003, in this case.

3. I was in possession of the claimed invention prior to April 1, 2000. This is evidenced by the results of flow cytometry experiments (Exhibit A) that were performed under my direction and control prior to April 1, 2000.

4. Exhibit A contains data from FACS analysis of the unrestricted somatic stem cells (USSCs) isolated according to the methods described in Example 1 of the specification. Specifically, blood samples were collected from human umbilical cords immediately after birth using collections bags containing citrate phosphate dextrose. The blood mononuclear cells were isolated using Ficoll density gradient centrifugation and cultured according to one of the four conditions described in the specification at page 17, lines 1-12. In order to obtain a sufficient number of cells for FACS, cultured mononuclear cells were expanded according to the culture method provided in the specification at page 17, last paragraph.

5. A profile of cell surface markers was determined for the expanded mononuclear cells using FACS. The results are summarized below and compared to those taught by Erices.

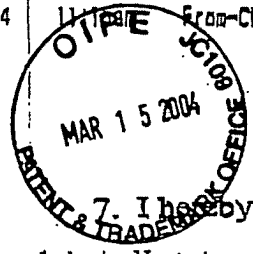
Cell Surface Marker	Exhibit A	Cells Described in the Specification	Mesenchymal-like Cells of Erices
IgG (negative control)	page 1	negative	negative
Markers Recited in the Pending Claims			
CD13	page 2, middle	positive	positive
CD14	page 2, right page 4, middle	negative	negative
CD29	page 6, left	positive	positive
CD35	---	negative	N.D.



CD44	page 4, left	positive	N.D.
CD45	page 3, middle page 4, right page 11, middle	negative	negative
CD49e	page 3, left	positive	positive
Other Markers Described in the Specification or by Ericcs			
HLA I	page 2, left	positive	N.D.
CD31	page 9, middle	negative	negative
CD34	page 6, right page 8, right page 11, right	negative	negative
CD49d	---	---	negative
CD54	---	---	positive
CD90	---	---	positive
CD106	---	---	negative
α -smooth muscle actin (ASMA)	---	---	positive
von Willebrand factor	---	---	negative
SH-2	page 10, left	positive	positive
SH-3	page 9, left	positive	positive
SH-4	---	---	positive
SSEA-4	page 5, left	positive	N.D.

N.D. = not determined

6. As is shown in Exhibit A, prior to April 1, 2000, I had isolated and characterized the unrestricted somatic stem cells (USSCs) of the presently claimed invention.



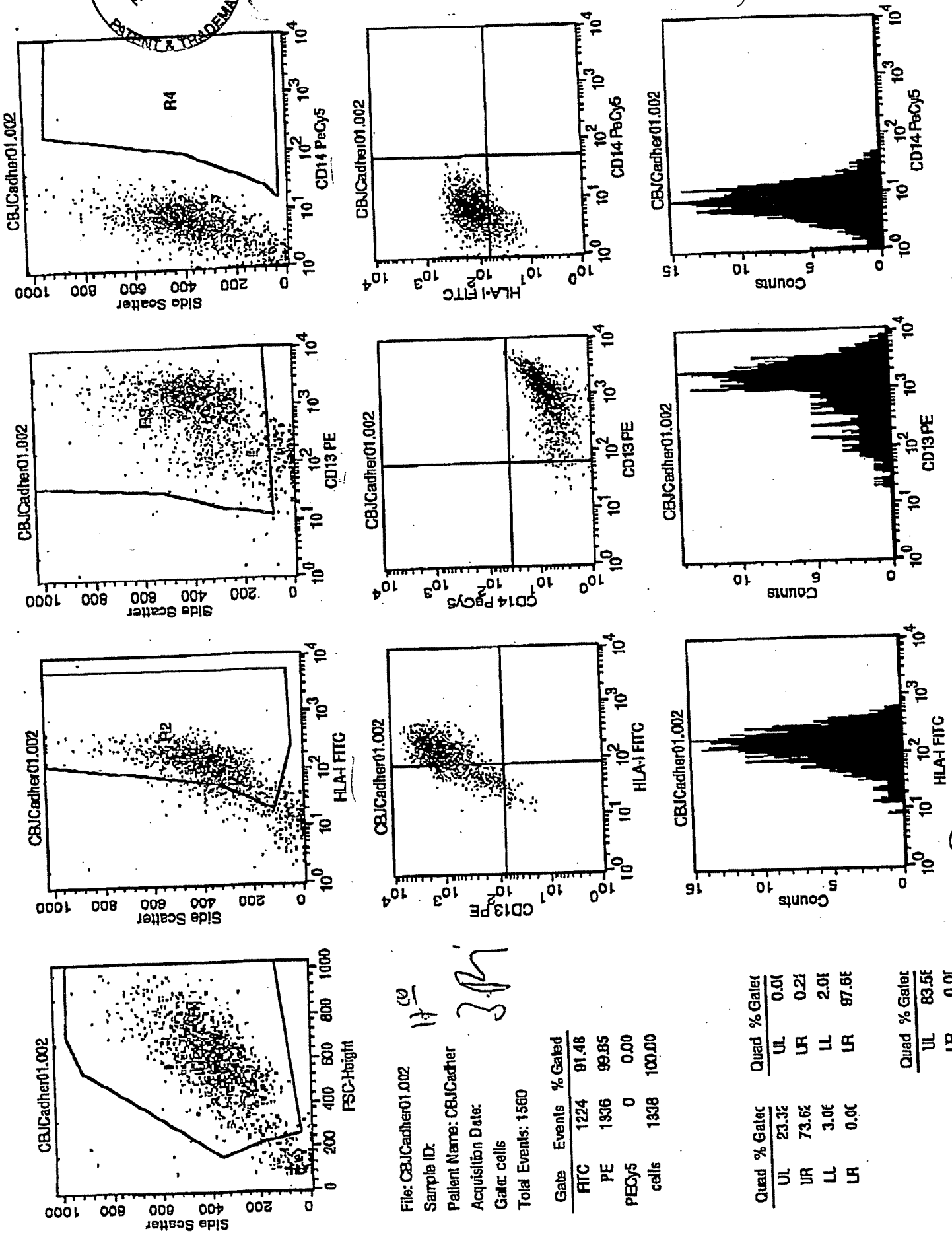
7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Date: March 10, 2004

Peter Wernick
Dr. Peter Wernick



Exhibit A Page 1



File: CBJCadher01.002

Sample ID:

Patient Name: CBJCadher

Acquisition Date:

Gate: cells

Total Events: 1560

Gate	Events	% Gated
FITC	1224	91.48
PE	1336	99.95
PECy5	0	0.00
cells	1338	100.00

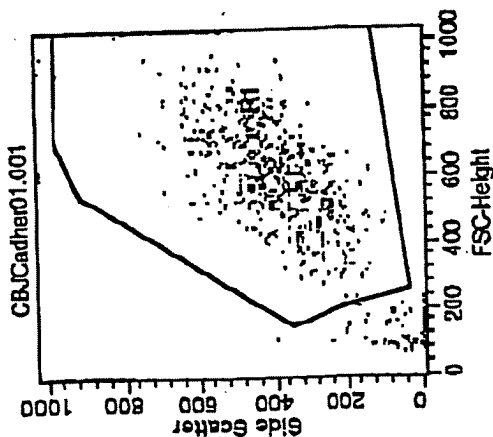
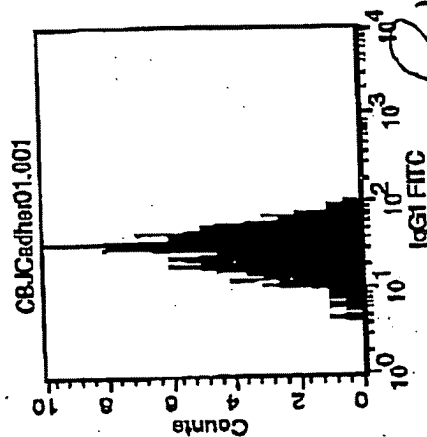
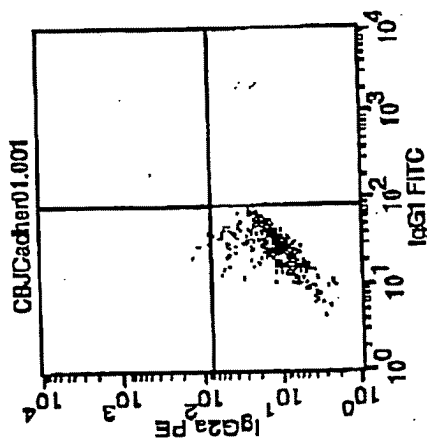
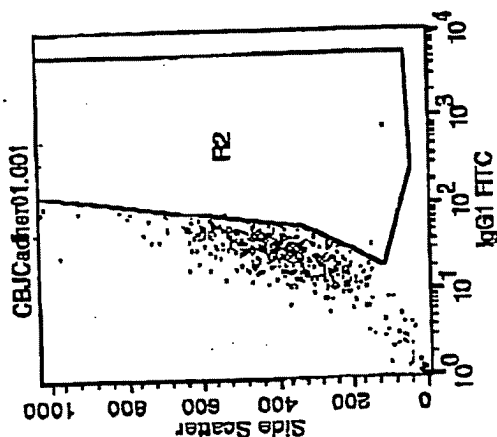
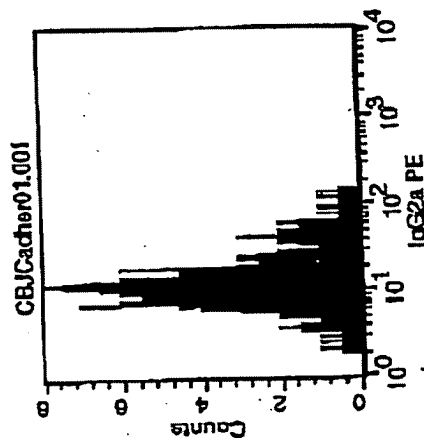
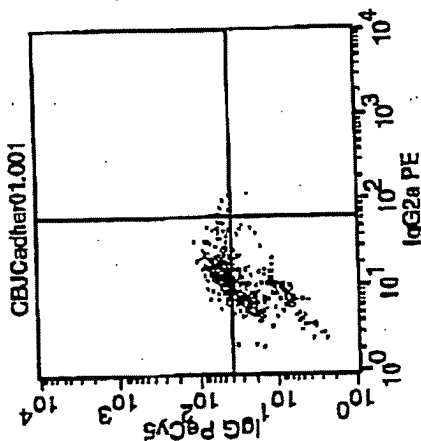
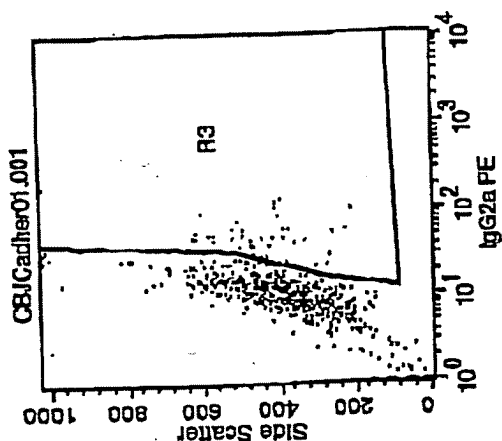
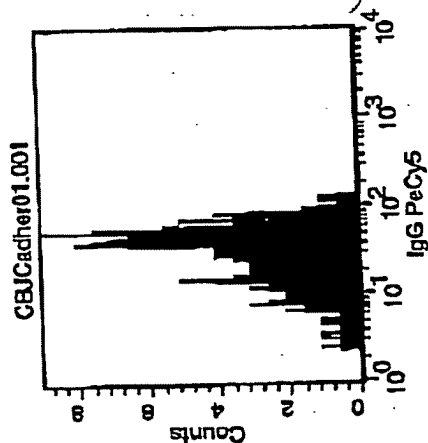
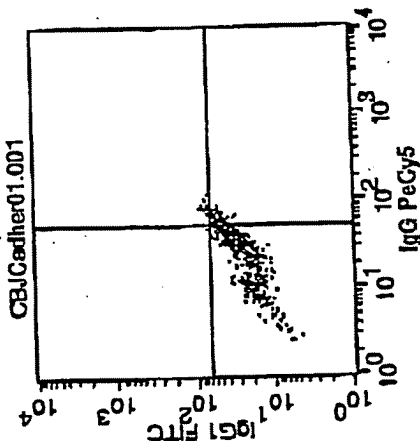
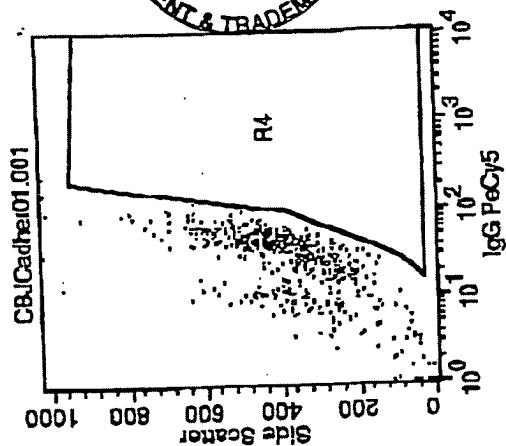
Quad	% Gated	Quad	% Gated
UL	23.32	UL	0.01
UR	73.62	UR	0.21
LL	3.06	LL	2.01
LR	0.00	LR	97.81

Quad	% Gated	Quad	% Gated
UL	83.51	UL	0.01
UR	0.01	UR	0.01
LL	16.44	LL	16.44
LR	0.01	LR	0.01

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MAR 15 2004
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Exhibit A Page 2



File: CBJCadher01.001

Sample ID:

Patient Name: CBJCadher

Acquisition Date:

Gate: cells

Total Events: 585

Gate	Events	% Gated
FITC	5	1.00
PE	48	9.16
PECy5	0	0.00
cells	502	100.00

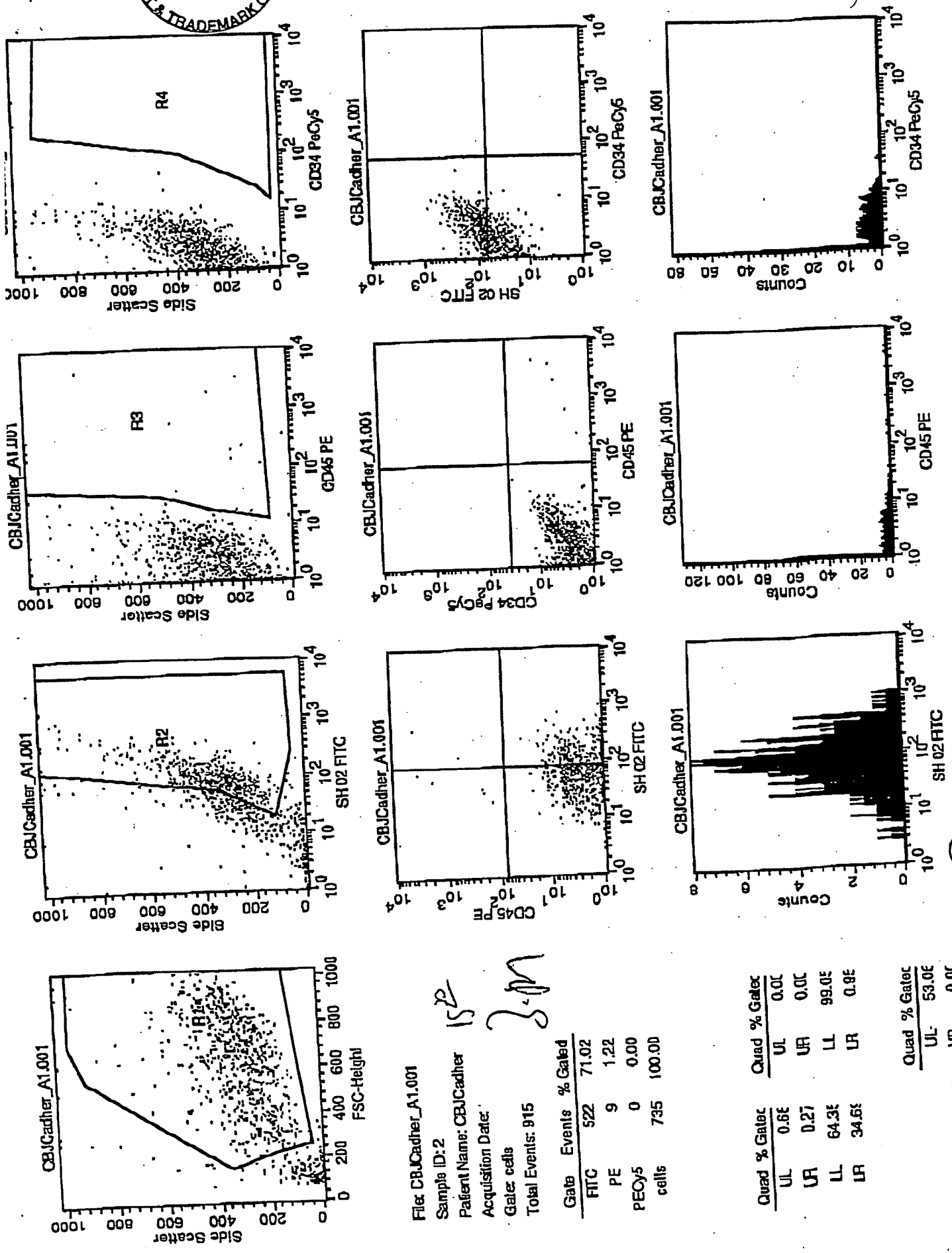
Quad	% Gated
UL	42.25
UR	1.00
LL	56.57
LR	0.20

Quad	% Gated
UL	0.20
UR	2.50
LL	85.00
LR	12.15

Ren

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Exhibit A Page 3



File: CBJCadher_A1.001
 Sample ID: 2
 Patient Name: CBJCadher
 Acquisition Date:
 Gate: cells
 Total Events: 915

Gate	Events	% Gated
FITC	522	71.02
PE	9	1.22
PeCy5	0	0.00
cells	735	100.00

Quad % Gated		Quad % Gated	
UL	0.6%	UL	0.0%
UR	0.27%	UR	0.0%
LL	64.3%	LL	99.0%
LR	34.6%	LR	0.9%

Quad % Gated		Quad % Gated	
UL	53.0%	UL	0.0%
UR	0.0%	UR	46.94%
LL	46.94%	LL	0.0%
LR	0.0%	LR	0.0%

Renel

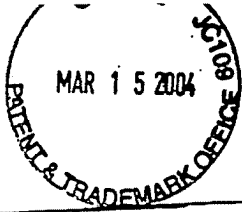
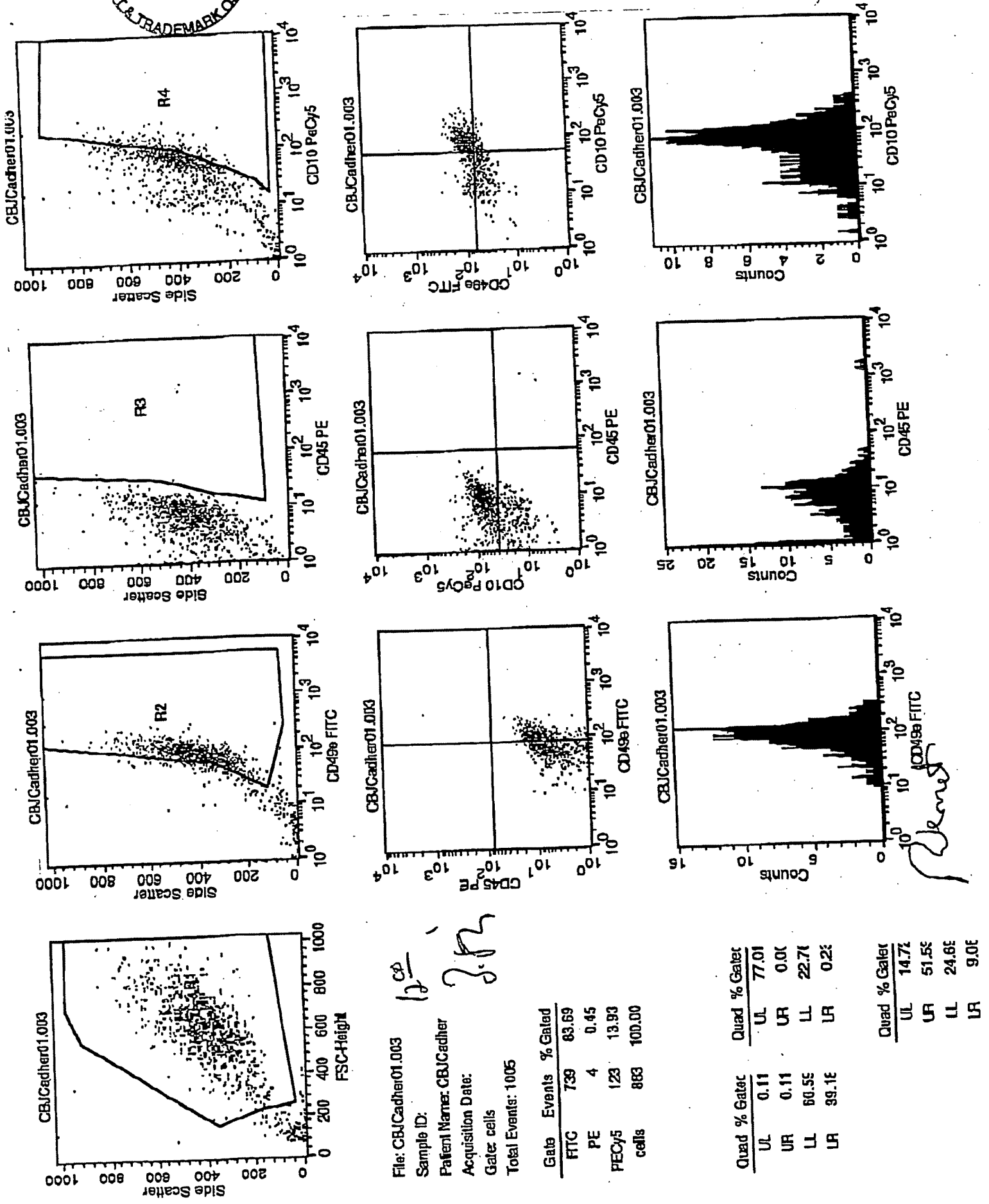


Exhibit A Page 4



12-3-03

File: CBU/Cadher01.003
Sample ID:
Patient Name: CBU/Cadher
Acquisition Date:
Gate: cells
Total Events: 1005

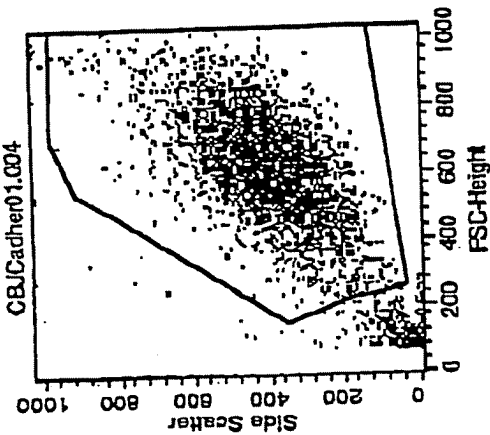
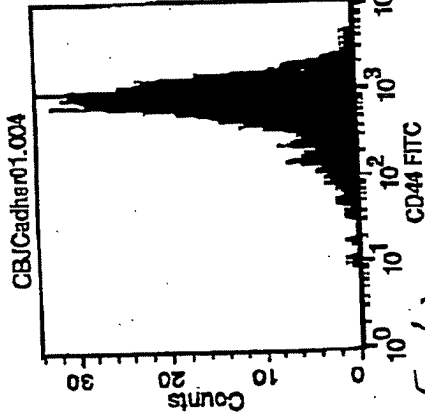
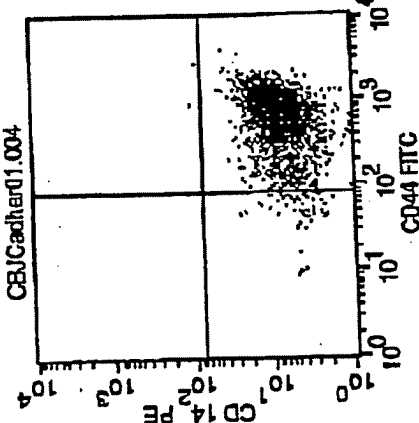
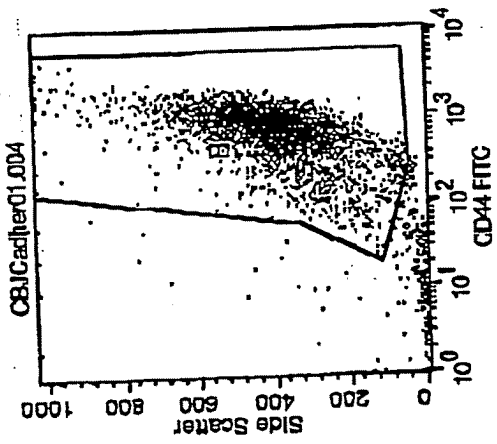
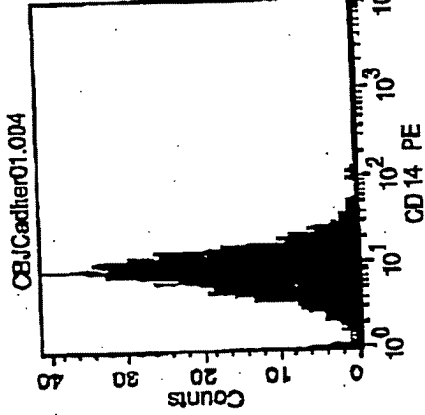
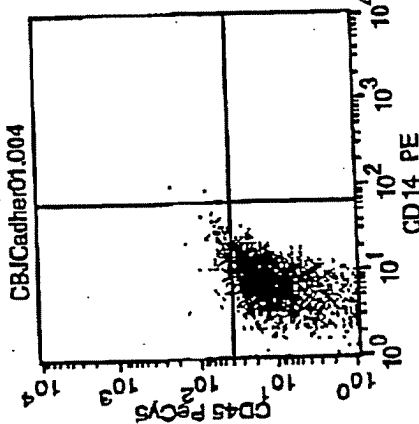
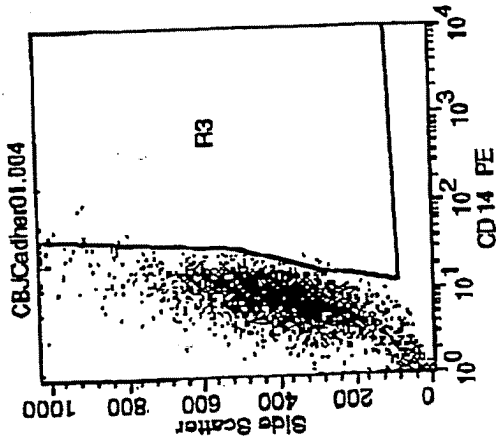
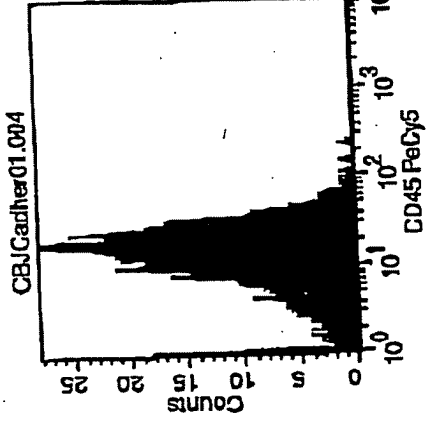
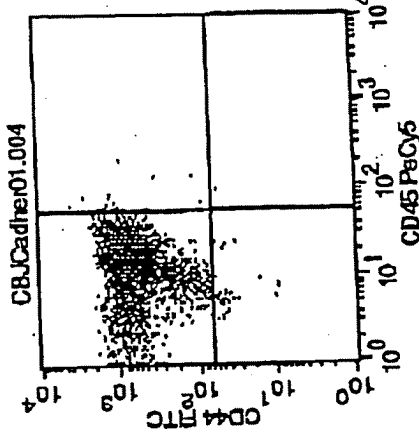
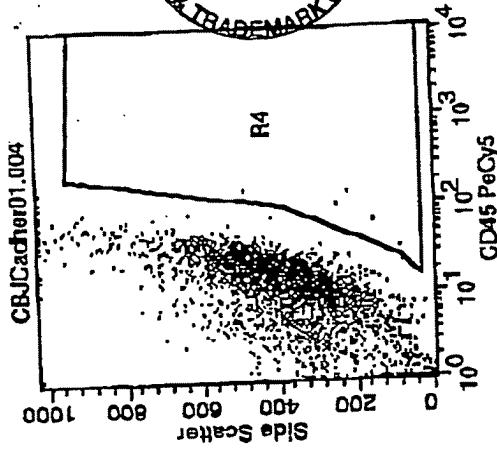
Gate	Events	% Gated
FITC	739	83.69
PE	4	0.45
PeCy5	123	13.93
cells	883	100.00

Quad	% Gated	Quad	% Gated
UL	0.11	UL	77.01
UR	0.11	UR	0.00
LL	60.55	LL	22.71
LR	39.18	LR	0.28

Quad	% Gated	Quad	% Gated
UL	14.72	UL	14.72
UR	51.58	UR	51.58
LL	24.68	LL	24.68
LR	9.02	LR	9.02

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Exhibit A Page 5



File: CBJCadher01.004
Sample ID: 172
Patient Name: CBJCadher
Acquisition Date: J. J. M.
Gate: cells
Total Events: 3690

Gate	Events	% Gated
FITC	3281	99.70
PE	16	0.49
PECy5	5	0.15
cells	3291	100.00

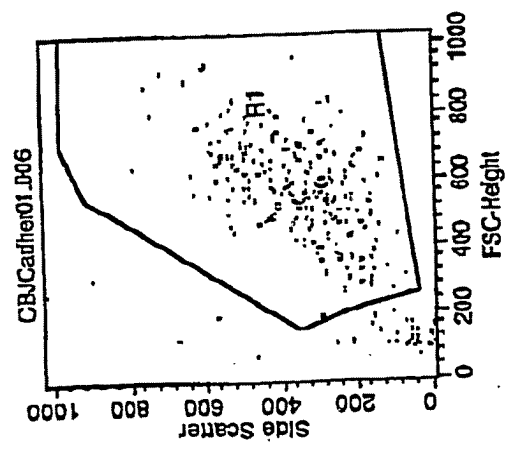
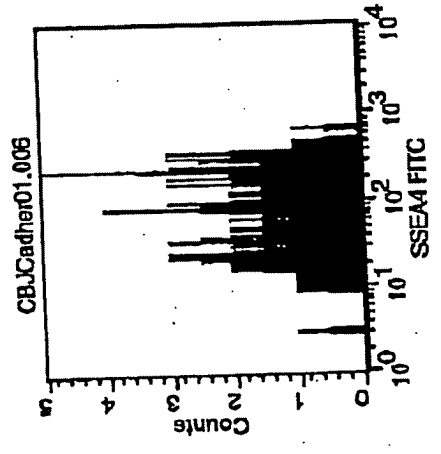
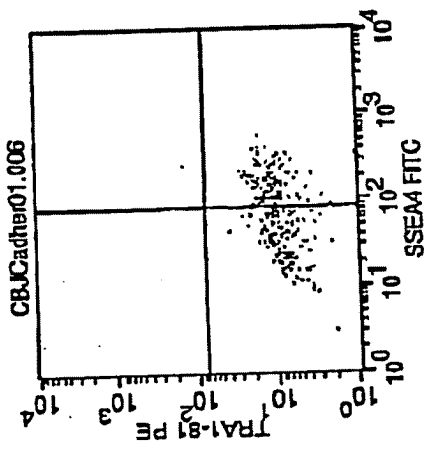
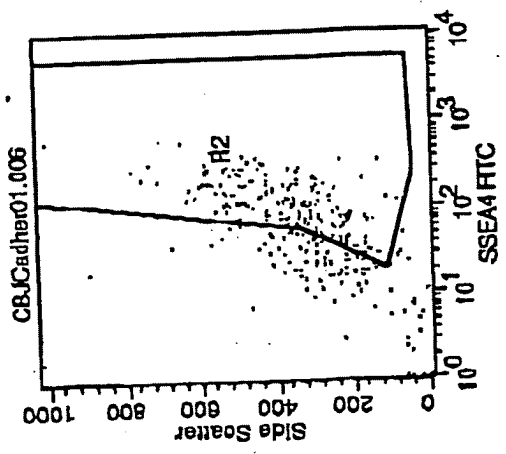
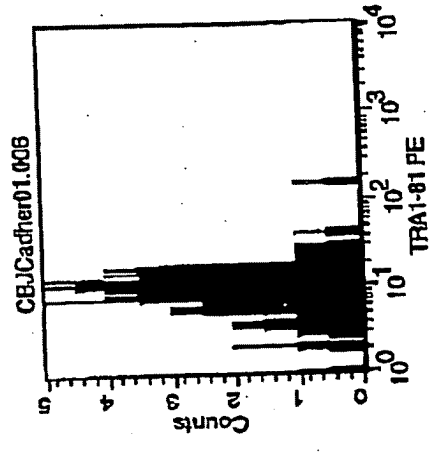
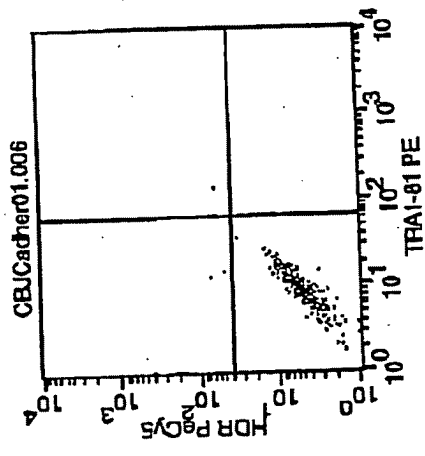
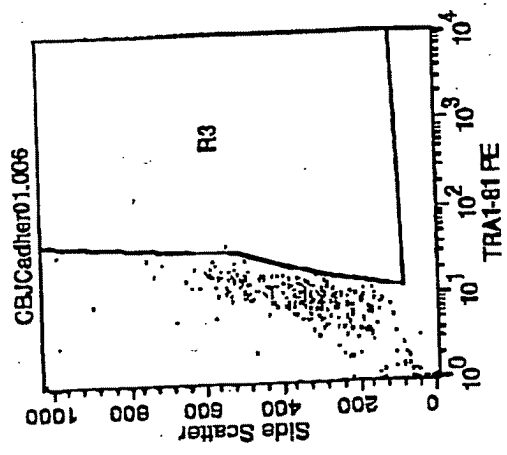
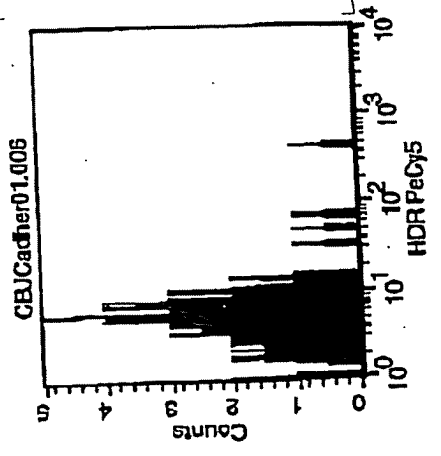
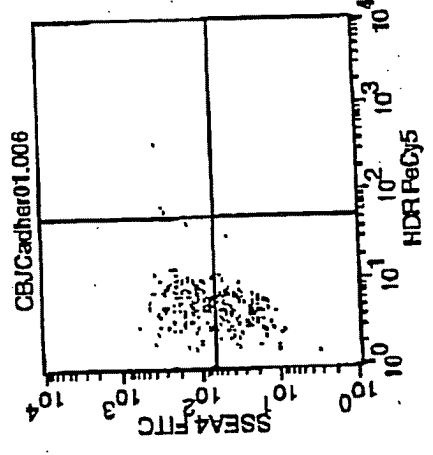
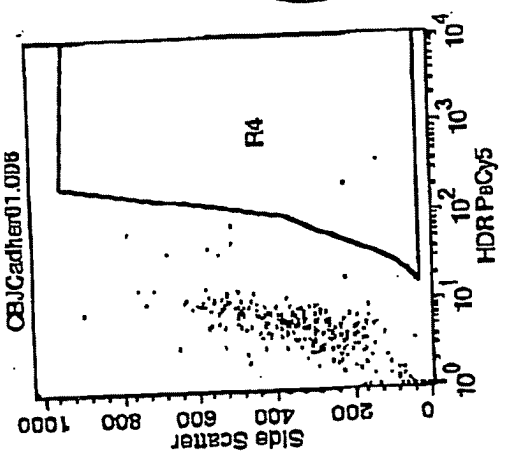
Quad	% Gate	Quad	% Gate
UL	0.00	UL	4.21
UR	0.00	UR	0.00
LL	1.94	LL	96.89
LR	97.99	LR	0.00

Quad	% Gate
UL	98.30
UR	0.67
LL	1.00
LR	0.00

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Exhibit A Page 6



File: CBJCadher01.006
Sample ID: *14*
Patient Name: CBJCadher
Acquisition Date: *3-11*
Gate: cells
Total Events: 300

Gate	Events	% Gated
FITC	171	70.08
PE	3	1.23
PECy5	1	0.41
cells	244	100.00

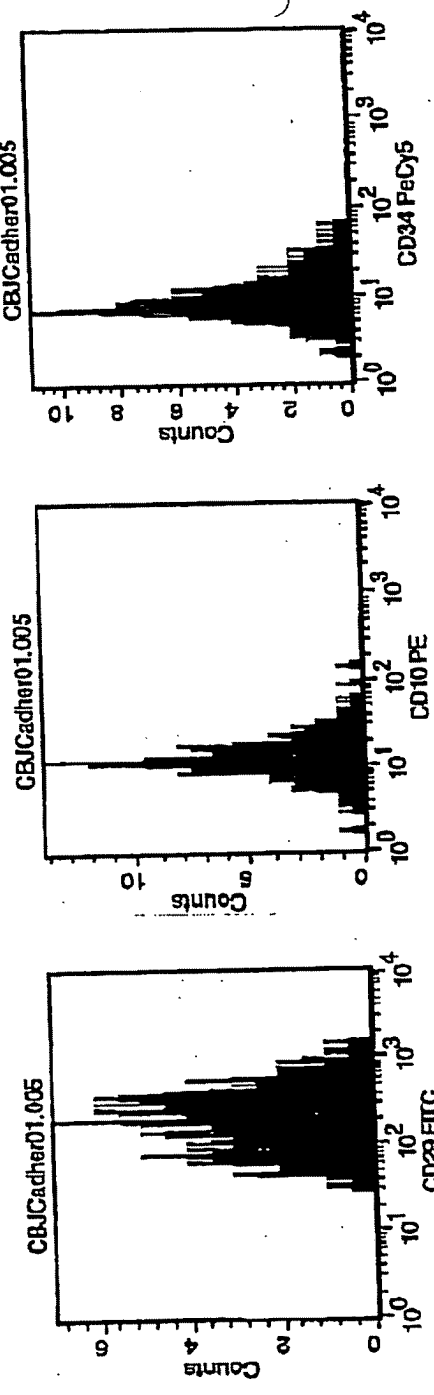
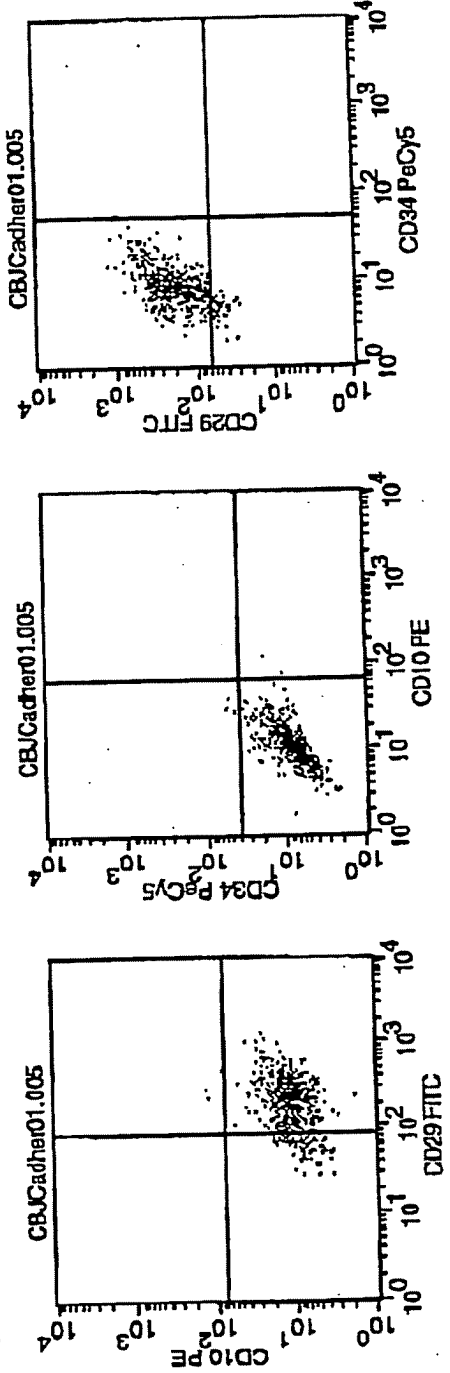
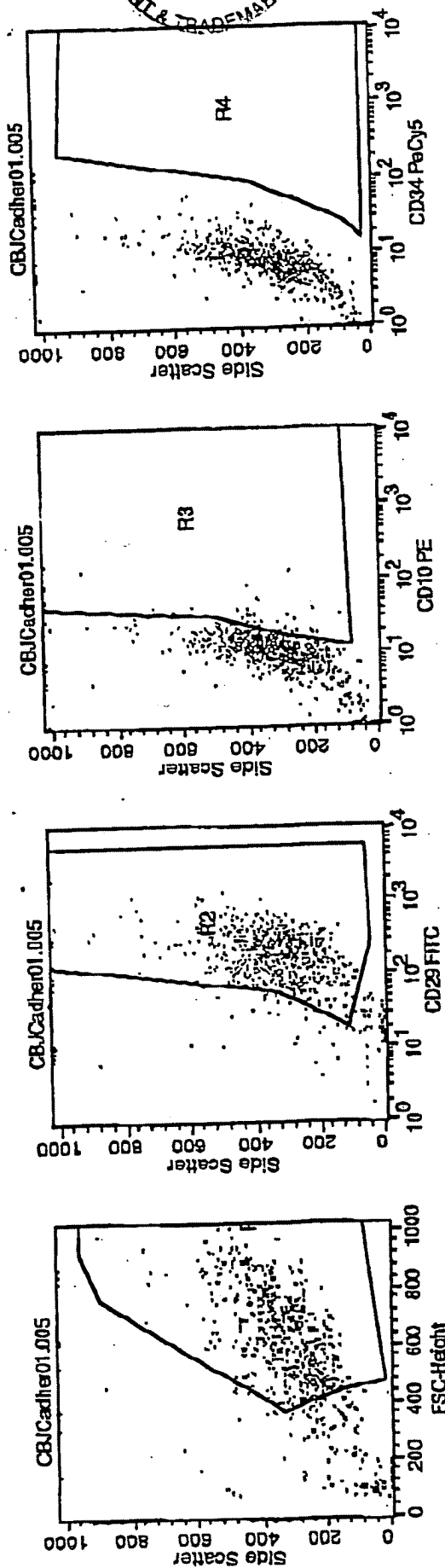
Quad	% Gated
UL	0.00
UR	0.41
LL	51.64
LR	47.95

Quad	% Gated
UL	58.15
UR	1.23
LL	42.82
LR	0.00

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Exhibit A Page 7



File: CBJCadher01.005
Sample ID: 11
Patient Name: CBJCadher
Acquisition Date: 3/8/04
Gate: cells
Total Events: 705

Gate	Events	% Gated
FITC	537	97.64
PE	33	6.00
PeCy5	0	0.00
cells	550	100.00

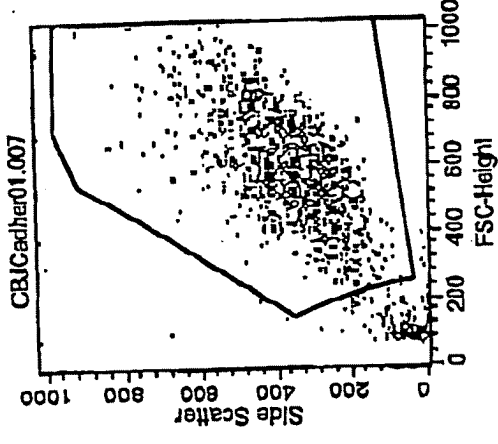
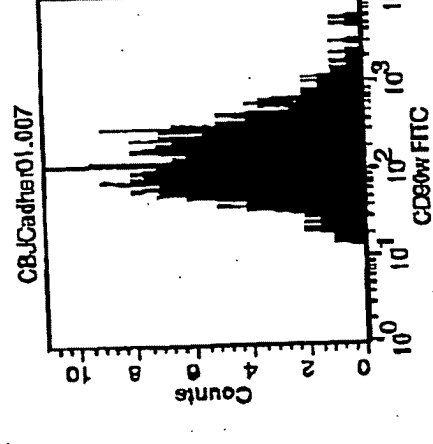
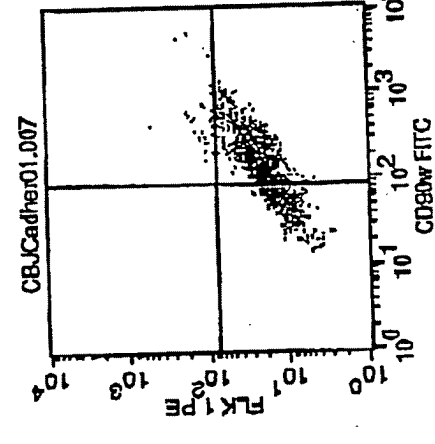
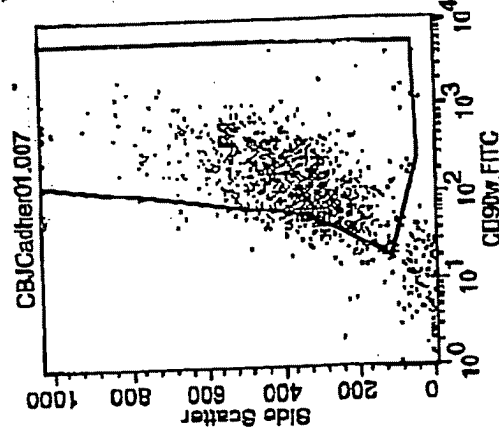
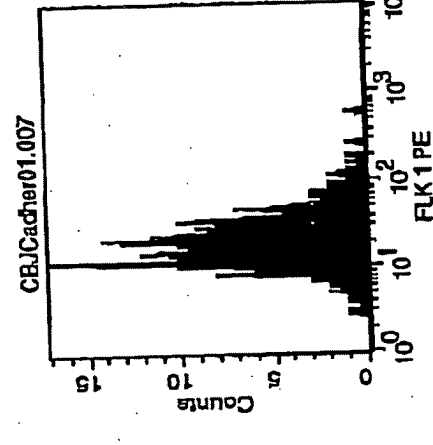
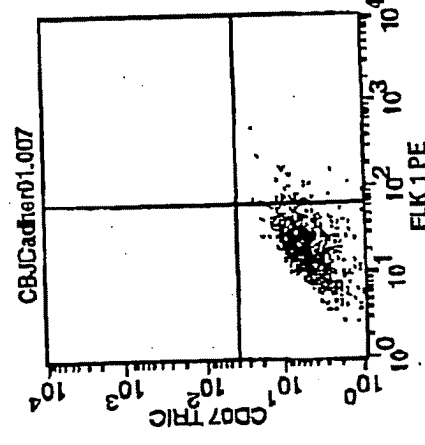
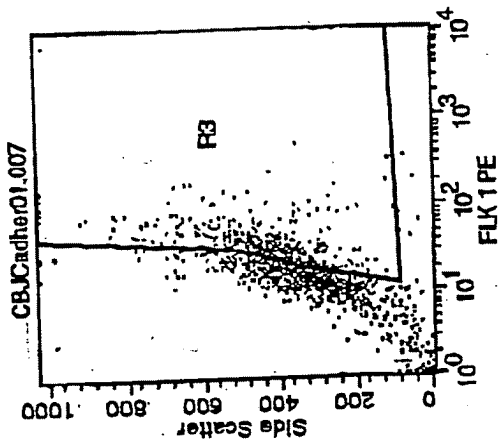
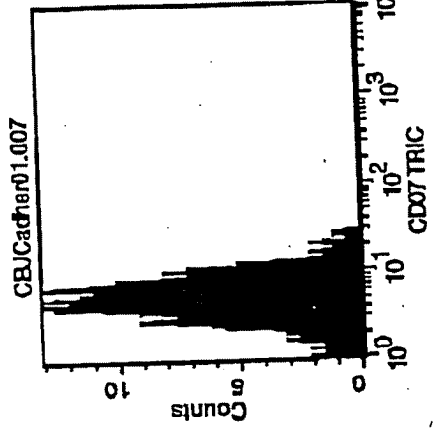
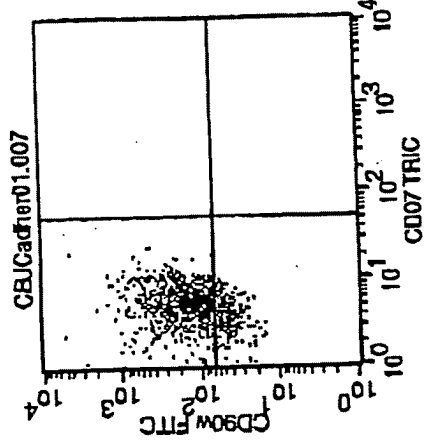
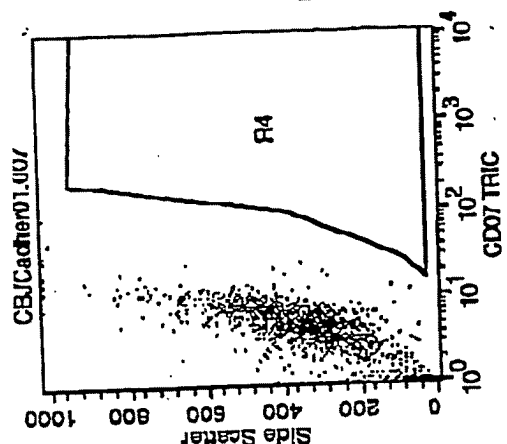
Quad	% Gate
UL	0.00
UR	0.50
LL	16.50
LR	82.91

Quad	% Gate
UL	61.80
UR	0.10
LL	8.00
LR	0.00

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Exhibit A Page 8



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File: CBJCadher01.007

Sample ID:

Patient Name: CBJCadher

Acquisition Date:

Gate: cells

Total Events: 1320

Gate	Events	% Gated
FITC	1030	89.88
PE	419	36.56
PECy5	0	0.00
cells	1146	100.00

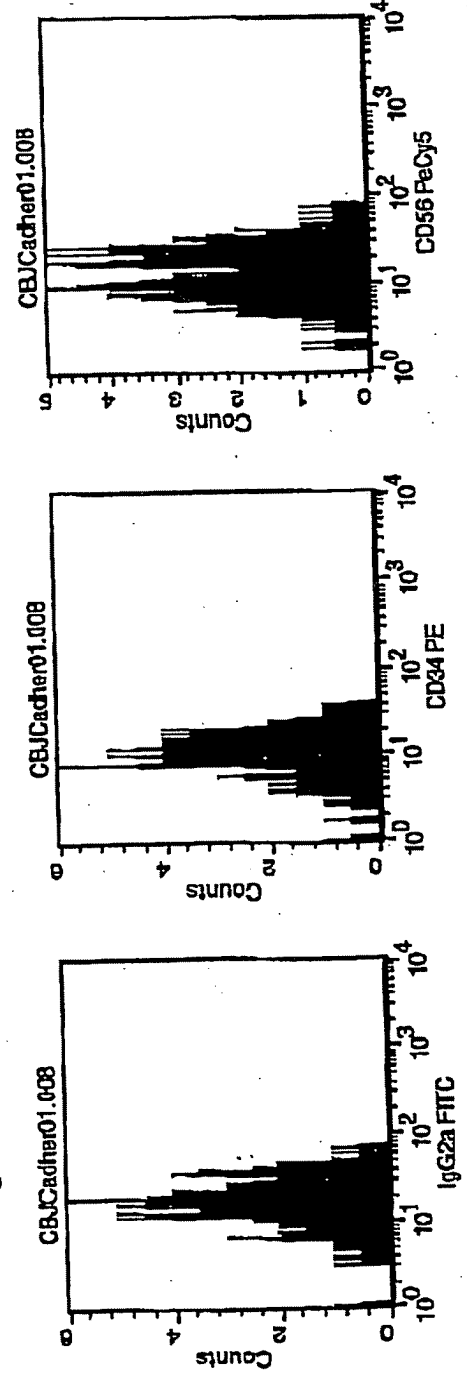
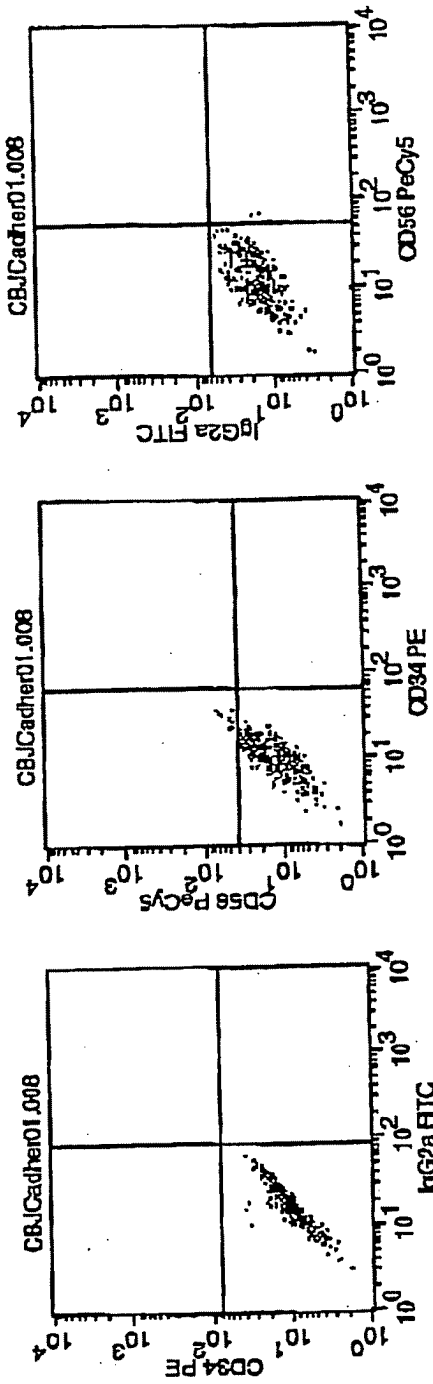
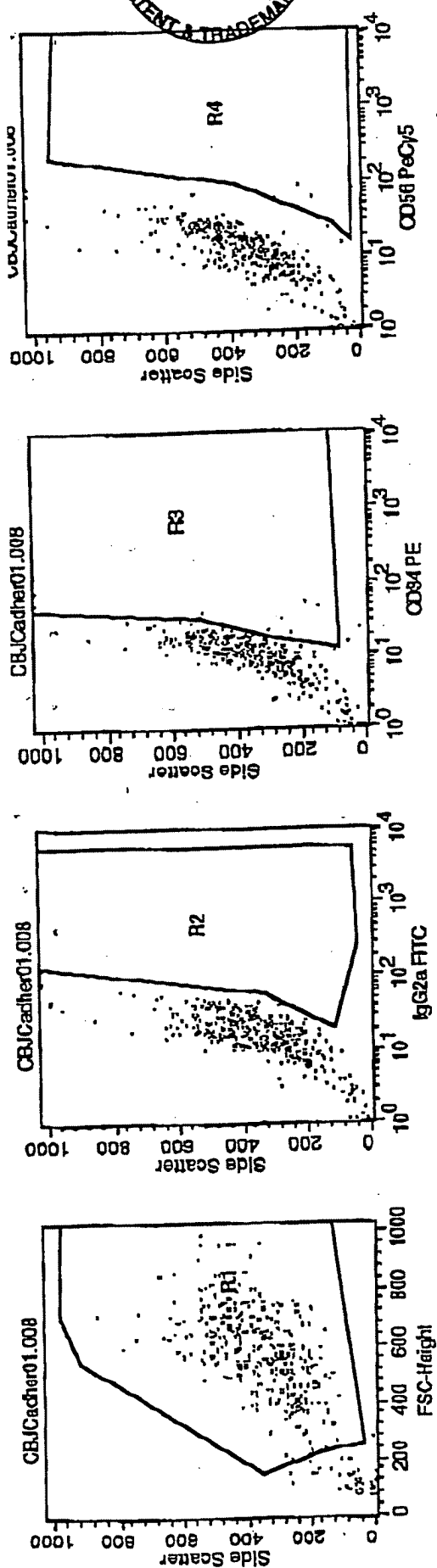
Quad	% Gate
UL	0.00
UR	0.00
LL	98.16
LR	3.84

Quad	% Gate
UL	75.92
UR	0.00
LL	24.08
LR	0.00

J. W. Ward

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Exhibit A Page 9



Signature: J. N.

File: CBJ/Cadher01.008

Sample ID:
Patient Name: CBJ/Cadher
Acquisition Date:
Gate: cells
Total Events: 375

Gate	Events	% Gated
FITC	0	0.00
PE	7	2.13
PeCys5	1	0.30
cells	329	100.00

Quad	% Gate	Quad	% Gate
UL	0.00	UL	3.34
UR	0.00	UR	0.00
LL	100.00	LL	96.66
LR	0.00	LR	0.00

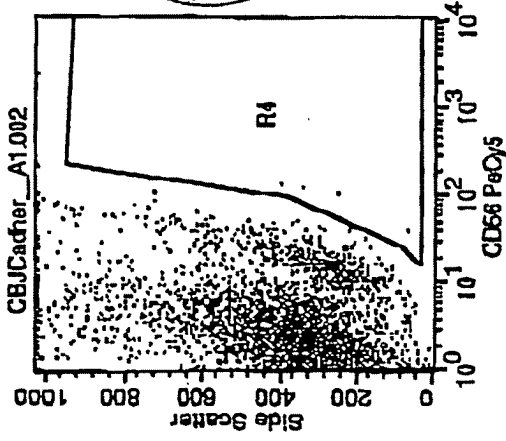
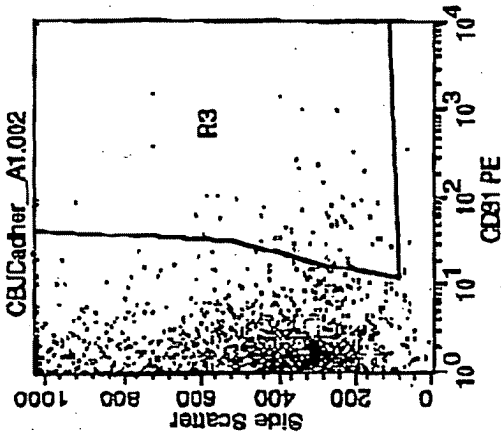
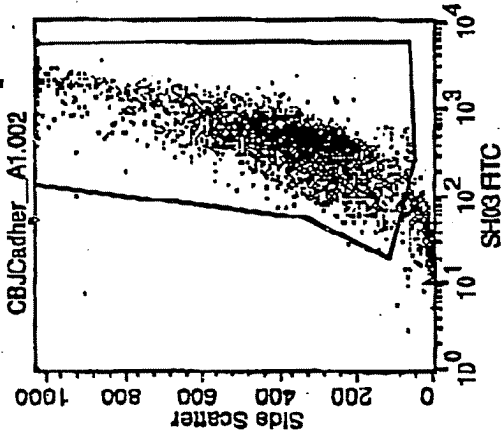
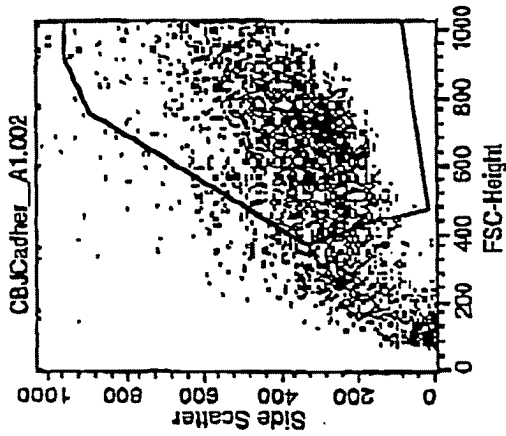
Quad	% Gate
UL	0.00
UR	0.00
LL	99.00
LR	0.91

Signature: J. N.

Exhibit A

Page 10

OIP
MAR 15 2002
15:26



File: CBJCadher_A1.002

Sample ID: 2

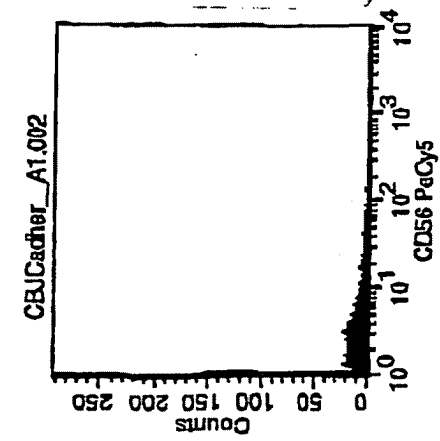
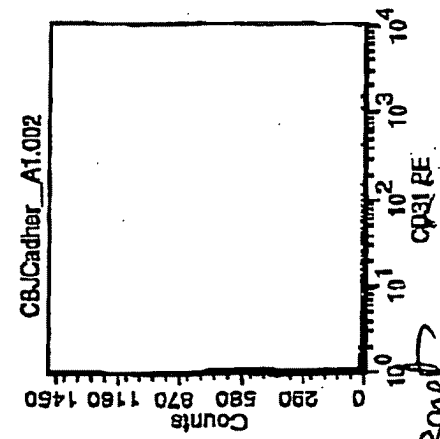
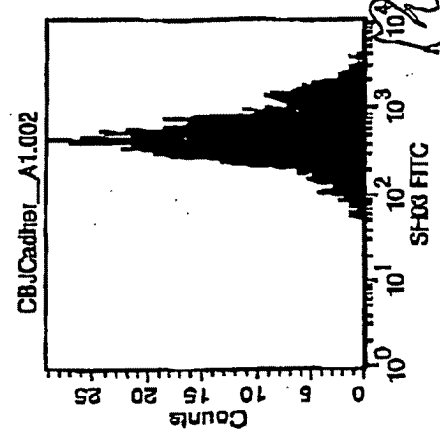
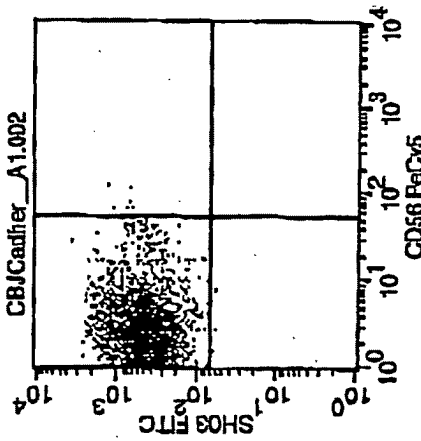
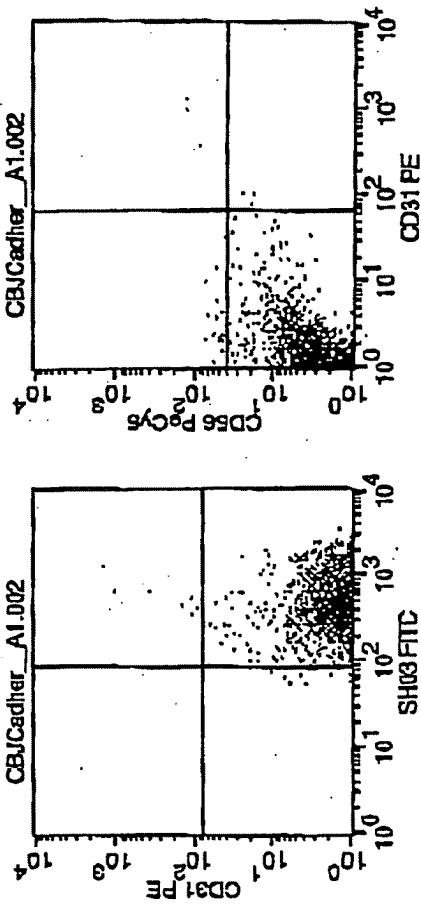
Patient Name: CBJCadher

Acquisition Date:

Gate: cells

Total Events: 3855

Gate	Events	% Gated
FITC	2692	99.93
PE	25	0.93
PeCys	2	0.07
cells	2694	100.00



Quad	% Gated	Quad	% Gated
UL	0.00	UL	1.00
UR	0.30	UR	0.10
LL	0.40	LL	98.60
LR	99.20	LR	0.10

Quad	% Gated
UL	99.50
UR	0.30
LL	0.11
LR	0.00

15-2
2-4
Mendet